

Custom Media Production/Pricing Request Form

Date: February 27, 2007

The intent of this form is to gather the necessary information to produce a quality product based upon the mutual requirements of _____ and Lonza, Inc.

Request submitted for (check one):	<input type="checkbox"/> Pricing Only	<input type="checkbox"/> Production
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Customer Information	
Institution Name	
Representative Name	
Title	
Address	
Country	
Telephone	
Fax	
Email	
Technical Advisor	

Product Information	
Request for	<input type="checkbox"/> Liquid Media ¹ <input type="checkbox"/> Powdered Media ² <input type="checkbox"/> Empty Bag
Product Requested	
Is product intended for Cell Therapy use?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Quantity requested	

¹For Liquid Media a fee of \$2,000 may apply to batches below 500 Liters.

²Minimum Order Requirement for Powdered Medium is 8 kg.

Assigned by Lonza, Inc:	
Custom Production Request Number	
Lonza Catalog Number	



Containers for Liquid Media Requests				
PLASTIC BOTTLES	Platinum Ultrapak™ Flexible Systems		ProEVA™ Bioprocessing Bags	CARBOYS
<input type="checkbox"/> 1 Liter	<input type="checkbox"/> 1 Liter	<input type="checkbox"/> 50 Liters	<input type="checkbox"/> 1 Liter	<input type="checkbox"/> 10 Liter
<input type="checkbox"/> 500 ml	<input type="checkbox"/> 5 Liters	<input type="checkbox"/> 100 Liters	<input type="checkbox"/> 5 Liters	<input type="checkbox"/> 18 Liter
<input type="checkbox"/> 100 ml	<input type="checkbox"/> 10 Liters	<input type="checkbox"/> 200 Liters	<input type="checkbox"/> 10 Liters	<input type="checkbox"/> 22 Liter
Closure on bottles is a standard 38 mm cap	<input type="checkbox"/> 20 Liters	<input type="checkbox"/> Other:	<input type="checkbox"/> 20 Liters	Standard Carboy Closures
<input type="checkbox"/> Other	Outer Packaging <input type="checkbox"/> Cardboard <input type="checkbox"/> Plastic Bin <input type="checkbox"/> Plastic Pallets			<input type="checkbox"/> Screw-neck Cap with shrink-wrap <input type="checkbox"/> Rigging Cap with venting filter, hose barb connection + female luer lock connector
Fill Volume:				
Productions are within 5% overfill variance unless otherwise indicated.				
If an alternative overfill percentage is required, please indicate the requirement:				
Customer Samples Required? <input type="checkbox"/> No <input type="checkbox"/> Yes; Indicate quantity: Volume:				

Plastic Containers for Powdered Media Requests	
<input type="checkbox"/> 10 Liter <input type="checkbox"/> 50 Liter <input type="checkbox"/> 100 Liter <input type="checkbox"/> Other:	
Fill Weight:	
Customer Samples Required? <input type="checkbox"/> No <input type="checkbox"/> Yes; Indicate quantity: Volume:	
Productions are within 1% overfill variance.	

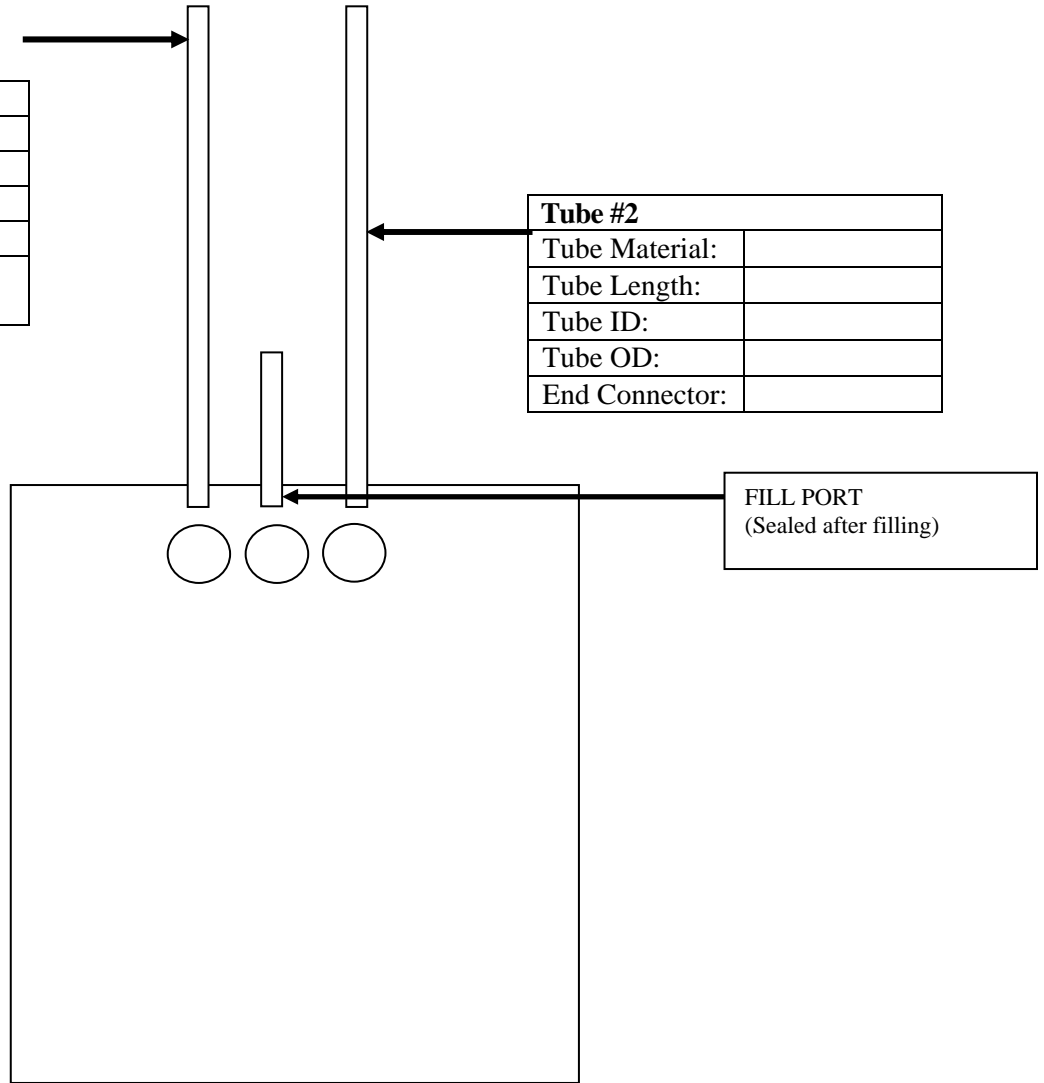
Additional Information	<input type="checkbox"/> N/A
Please indicate any other special packaging requirements you might have for your product that have NOT been addressed in the preceding parts of this form:	

Tube # 1	
Tube Material:	
Tube Length:	
Tube ID:	
Tube OD:	
End Connector:	

Tube #2	
Tube Material:	
Tube Length:	
Tube ID:	
Tube OD:	
End Connector:	

BAG SIZE	
FILL VOL	

Additional Information:



ADDITIONAL TUBES IF REQUIRED:

Tube #3		Tube #4		Tube #5	
Tube Material		Tube Material		Tube Material	
Tube Length:		Tube Length:		Tube Length:	
Tube ID:		Tube ID:		Tube ID:	
Tube OD:		Tube OD:		Tube OD:	
End Connector:		End Connector:		End Connector:	

Is this bag design to be treated with confidentiality? Yes No

Material Information	
Special request regarding raw material (e.g. a specific vendor or level of quality)	
Should the raw material used be linked to a particular Pharmacopoeia?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If applicable, state Pharmacopoeia to use:	
Is there any requirement concerning the origin of the raw material?	<input type="checkbox"/> None <input type="checkbox"/> Raw material must be non-animal <input type="checkbox"/> Yes (specify origin)
Is 9 CFR testing required for any animal-origin raw materials?	<input type="checkbox"/> Yes <input type="checkbox"/> No

Note:

All chemicals used in production will be from Lonza, Inc.'s standard inventory unless otherwise requested. Lonza, Inc. reserves the right to formulate custom media from scratch or from basal powdered media. Customers will be informed and may be required to purchase full container amounts of chemicals that must be special ordered. Powdered media formulations may be adjusted by the substitution of anhydrous, free-base, or salt forms of certain chemicals to reduce moisture and enhance solubility. When made, the substitutions are equivalent with regard to the molarity/molality of the required component of the chemicals.

Quality Control Clearance Specifications	
Please indicate all tests required for your product:	
<input type="checkbox"/> Sterility	Negative per current USP Sterility Guidelines (Liquid media only)
<input type="checkbox"/> Moisture	<2% (Powdered media only)
Note: Specifications for the following assays can only be developed when a history of producing the custom product has been established. If any of the following tests are selected, please provide target ranges, if known. The values listed below will be used as target points for information only (FIO) until an adequate production history has been obtained.	
<input type="checkbox"/> pH (at room temp)	Target Range:
<input type="checkbox"/> Osmolality (mOsm/kg H ₂ O, at room temp)	Target Range:
<input type="checkbox"/> Endotoxin (EU/ml, Liquid media only)	Target Range:
<input type="checkbox"/> Bioburden (Powdered media only)	Target Range:
<input type="checkbox"/> Cell Growth Promotion	Target Range:
<input type="checkbox"/> Mycoplasma	Negative
Please list below any additional testing required. Include a reference for the method that is required for the additional QC test. Provide the target specification range, if known.	
The following documents can be provided for additional fees (prices provided upon request):	
<input type="checkbox"/> Full Dossier: Master Table, CoA on raw material, DHR, and Chemistry Protocol <input type="checkbox"/> Master Table <input type="checkbox"/> Non-animal origin (NAO) statement	

Validation/Certification

This product shall be manufactured within agreed upon specification and in accordance with Good Manufacturing Practices for Medical Devices (21 CFR 820). Sterilization procedures and aseptic processing have been validated following FDA guidelines. All water in the production will be (USP/EP) Water for Injection (WFI) quality water. There will be a 10% or \$100 (whichever is greater) cancellation fee on all orders canceled prior to production. Any materials purchased for custom productions to satisfy a purchase order will be automatically billed to the customer should a cancellation be received. Cancellation is only possible up to 5 days before the scheduled production date. Sales are without any seller’s warranty or representation, expressed or implied, by usage or otherwise. All orders are subject to acceptance.

Shipping Information
Please indicate any extraordinary receiving or delivery requirements you might have, so that we may better coordinate your deliveries:
<input type="checkbox"/> N/A

Additional Information
Please indicate any other special requirements you might have for your product that have NOT been addressed in the preceding parts of this form:
<input type="checkbox"/> N/A

Approval

- I understand the above information and, in case of purchase order, I authorize the production of this product. I further understand that this production request will not be implemented until Lonza, Inc. has received an official purchase order number from my company or organization.
- Custom orders may yield a ±20% variance of the quantity requested. The customer will be required to purchase any positive variance. Allow 8-10 weeks after receipt of order for availability of first-time customs and 8 weeks after receipt of order of repeat customs.
- If entire lot is not shipped upon clearance, firm ship dates are required and must not exceed 6 months from date of clearance. At the end of six months, Lonza, Inc. reserves the right to ship and bill the remaining inventory or assess a one-time inventory carrying fee based on 2% of the total order at the time of initial reserve.
- It is understood that subsequent purchasers of the company that is bound by the form will be bound by the terms and conditions of this form just as the company who originally signed the form.
- I understand that if product falls outside of QC target points, I am obligated to purchase material, unless firm release specifications have been established.

Customer Signature: _____ **Date:** _____
(required for initial production run)

Note: Please review this form before forwarding it, since missing or incomplete information may result in production delays.